

REMARKS

1. The Examiner is thanked for withdrawing previous rejections under 35 U.S.C. §§ 102 and 103(a), and is also thanked for finding allowable subject matter in Claims 15 and 22 if they are rewritten in independent format to include all the limitations of the claims from which they depend. The application was filed with 61 claims, of which Claims 27-61 have been withdrawn. Claims 1-26 remain pending in the application.

2. Claims 1-4, 6, 7, 12, 14, 16, 17 and 24-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. 5,944,684 to Martin Roberts et al. ("Roberts"). Claims 5 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Roberts. Claims 8-10 and 18-19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Roberts in view of U.S. Pat. No. 4,229,299 to Savitz. Claims 11 and 20-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Roberts in view of U.S. Pat. No. 5,685,989 to Nikolai Krivitski et al. ("Krivitski"). No rejection of Claim 23 was found. Claim 23 depends from allowable Claim 22 and thus appears to be allowable.

2. Claims 1-4, 6, 7, 12, 14, 16, 17 and 24-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. 5,944,684 to Martin Roberts et al. ("Roberts"). The rejection cites Fig. 2 of Roberts. Applicants traverse the rejection, because Roberts does not teach the Claim 1 element of "a second fluid loop including a second pump and a medical fluid regenerator." In addition, several other elements of Claim 1, and many of the dependent claims are also not taught or suggested in Roberts.

The rejection states that Roberts teaches a second fluid loop, citing the second pump 8c and the medical fluid regenerator 11. As seen in Fig. 2, the patient loop includes in-dwelling catheter 2, connecting tube 3, first pump 8a, sieve 9, membrane 10, protein purifier 13, reservoir 14 and second pump 8c. Thus, pump 8c clearly belongs to the patient loop, not to a second fluid loop. The only second loop possible in Roberts Fig. 2 is the loop formed by membrane 10, the connecting tubing to ultrafiltrate purifier 11, the tubing connecting purifier 11 to reservoir 14, protein purifier 13, and then back to the membrane 10. This second loop does not contain a pump and thus fails to meet this requirement of the claimed second loop. In addition, the second loop has two branches, a first branch with a valve 16 and drain bag 7, for transfer of the

ultrafiltrate from membrane 10. However, the second loop also has a second branch that includes concentrate reservoir 12 and pump 8b.

Pump 8b cannot be the claimed "second pump" since it is not in a loop and thus cannot be in the "second fluid loop." One definition of a loop is "a curving or doubling of a line so as to form a closed or partly open curve within itself." Merriam-Webster's Collegiate Dictionary, 10th ed. at 688. The second loop is claimed as a closed loop, and a branch, such as Roberts' branch with reservoir 12 and pump 8b, is not part of the loop. Thus, Roberts' branch does not teach or suggest the claimed closed loop and Claim 1 is not anticipated. Claims 2-4, 6, 7, 12, 14, 16, 17 and 24-26 are allowable at least because they depend from allowable Claim 1.

3. Claims 5 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Roberts. Claim 5 is allowable at least because it depends from allowable Claim 1. As to Claim 13, depending from Claim 1, the rejection states that Roberts teaches or suggests the elements of the claim because blood circulates in the patient and therefore blood is circulating in the patient fluid loop. Office Action, p. 5, line 19, to p. 6, line 1, citing Roberts, col. 7, lines 1-4. Applicants traverse the rejection. Claim 13 clearly intends hemodialysis. The cited passage from Roberts describes peritoneal dialysis, in which the toxins in the blood stream are dialyzed through the peritoneum of the patient. The patient fluid loop and first pump of Claim 1 continue to pump dialysis fluid to the peritoneum of the patient. The first pump does not pump blood, it pumps dialysis fluid. A passage describing peritoneal dialysis cannot teach or suggest hemodialysis. In any event, Claim 13 is allowable because it depends from allowable Claim 1.

4. Claims 8-10 and 18-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Roberts in view of U.S. Pat. No. 4,229,299 to Savitz. Applicants traverse the rejections. Claim 8 recites a gas separator that removes gas from at least one of the first and second fluid loops. As described in the application, the patient loop typically contains dialysis fluid routed to and from the patient, while the second loop regenerates the dialysis fluid. The portion of Savitz that is cited in the rejection refers to Figs. 1 and 3, and accompanying text at col. 12-13. These passages concern the heating and degassing of city or other water that enters a system as make-up water for preparing additional dialysis solution. This water is not part of the patient loop in

which dialysis fluid is used, and is also not part of the second loop, in which the dialysis fluid is regenerated.

The reason for using Savitz' gas separator is that untreated water is known to have gas. Deaeration at the point of incoming water is an elementary step in preparing a medical fluid which will be placed into the patient's body. Once the gas is removed, and the water is made into dialysis solution, there is no need for further deaeration. Accordingly, one would not be motivated to go beyond Savitz's teaching of an incoming water gas separator to apply a gas separator to dialysis fluid, because the water used for the dialysis fluid has just been heated and deaerated. Thus, the combination of Savitz and Roberts would lead one to a gas separator for the incoming water, but not to a gas separator that removes gas from at least one of the patient fluid loop or the second fluid loop. Accordingly, Claim 8 is not obvious in view of Roberts and Savitz. Claims 9 and 10 are allowable for the same reasons. Claim 18-19 are allowable at least because they depend ultimately from allowable Claim 1.

5. Claims 11 and 20-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Roberts in view of U.S. Pat. No. 5,685,989 to Nikolai Krivitski et al. ("Krivitski"). The rejection cites Krivitski, col. 4, lines 24-27, as teaching optical, fluid volume and capacitance sensors. The teaching, however, is for detecting blood flow rather than any intrinsic properties of the blood. Claim 11 recites a multi-analyte sensor that monitors a concentration of electrolytes in the medical fluid, such as a dialysis fluid. Sensors for detecting fluid flow do not teach or suggest sensors that detect concentrations of electrolytes. Accordingly, Krivitski does not teach or suggest the elements of Claim 11. By the same reasoning, Claims 20 and 21 are also not obvious. The Examiner is respectfully requested to withdraw the rejections of Claims 11, 20 and 21.

6. For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. Applicants believe no fees are due. However, if any fees are due and payable, except for the issue fee, the Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,
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